

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
 0609.4780001/SRL/LBB

APPLICATION NO.
 09/475,158

APPLICANT
 GARDELLA *et al.*

FILING DATE
 December 30, 1999

GROUP
 To be assigned 1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
ew	AA1	4,675,189	06/23/1987	Kent <i>et al.</i>	424	490	02/08/1985
	AB1	4,698,328	10/06/1987	Neer <i>et al.</i>	514	12	12/05/1986
	AC1	4,736,866	04/12/1988	Leder <i>et al.</i>	800	1	06/22/1984
	AD1	4,761,406	08/02/1988	Flora <i>et al.</i>	514	86	06/06/1985
	AE1	5,527,772	06/18/1996	Holick, M.F.	514	12	06/28/1994
	AF1	5,840,690	11/24/1998	Holick, M.F.	514	12	06/06/1995
	AG1	5,977,070	11/02/1999	Piazza <i>et al.</i>	514	12	08/29/1995
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AI						Yes No
	AJ						Yes No
	AK						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

ew	AL	1	Abou-Samra, A.-B., <i>et al.</i> , "Non-Homologous Sequences of Parathyroid Hormone and the Parathyroid Hormone Related Peptide Bind to a Common Receptor on ROS 17/2.8 Cells," <i>Endocrinol.</i> 125:2215-2217 (1989)
	AM	1	Azarani, A., <i>et al.</i> , "Structurally Diverse N-terminal Peptides of Parathyroid Hormone (PTH) and PTH-related Peptide (PTHrP) Inhibit the Na ⁺ /H ⁺ Exchanger NHE3 Isoform by Binding to the PTH/PTHrP Receptor Type I and Activating Distinct Signaling Pathways," <i>J. Biol. Chem.</i> 271:14931-14936 (1996)
	AN	1	Bergwitz, C., <i>et al.</i> , "Full Activation of Chimeric Receptors by Hybrids between Parathyroid Hormone and Calcitonin," <i>J. Biol. Chem.</i> 271:26469-26472 (1996)
	AO	1	Bergwitz, C., <i>et al.</i> , "Residues in the Membrane-spanning and Extracellular Loop Regions of the Parathyroid Hormone (PTH)-2 Receptor Determine Signaling Selectivity for PTH and PTH-related Peptide," <i>J. Biol. Chem.</i> 272:28861-28868 (November 1997)
	AP	1	Bisello, A., <i>et al.</i> , "Parathyroid Hormone-Receptor Interactions Identified Directly by Photocross-linking and Molecular Modeling Studies," <i>J. Biol. Chem.</i> 273:22498-22505 (August 1998)

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Elaine Veran Wesley

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10/16/02

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>cu</i>	AL	<u>2</u>	Broadus, A.E. and Stewart, A.F., "Parathyroid Hormone-Related Protein Structure, Processing, and Physiological Actions," in <i>The Parathyroids Basic and Clinical Concepts</i> , Bilezikian <i>et al.</i> , eds., Raven Press Ltd., New York, New York (1994)
	AM	<u>2</u>	Caulfield, M.P., <i>et al.</i> , "The Bovine Renal Parathyroid Hormone (PTH) Receptor Has Equal Affinity for Two Different Amino Acid Sequences: The Receptor Binding Domains of PTH and PTH-Related Protein Are Located within the 14-34 Region," <i>Endocrinol.</i> 127:83-87 (1990)
	AN	<u>2</u>	Cleland, J.L., <i>et al.</i> , "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation," <i>Critical Rev. Ther. Drug. Carrier Sys.</i> 10:307-377 (1993)
	AO	<u>2</u>	Cohen, F.E., <i>et al.</i> , "Analogues of Parathyroid Hormone Modified at Positions 3 and 6. Effects on Receptor Binding and Activation of Adenyl Cyclase in Kidney and Bone," <i>J. Biol. Chem.</i> 266:1997-2004 (1991)
	AP	<u>2</u>	Colquhoun, D., Binding, gating, affinity, and efficacy: The interpretation of structure-activity relationships for agonists and of the effects of mutating receptors," <i>Br. J. Pharmacol.</i> 125:924-947 (November 1998)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

ew	AL	3	Dautzenberg, F.M., <i>et al.</i> , "Mapping of the ligand-selective domain of the <i>Xenopus laevis</i> corticotropin-releasing factor receptor 1: Implications for the ligand-binding site," <i>Proc. Natl. Acad. Sci. USA</i> 95:4941-4946 (April 1998)
	AM	3	Dempster, D.W., <i>et al.</i> , "Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocrine Rev.</i> 14:690-709 (1993)
	AN	3	Dempster, D.W., <i>et al.</i> , "Anabolic Actions of Parathyroid Hormone on Bone (Erratum)," <i>Endocrine Rev.</i> 15:261 (1994)
	AO	3	Gardella, T.J., <i>et al.</i> , "Mutational Analysis of the Receptor-activating Region of Human Parathyroid Hormone," <i>J. Biol. Chem.</i> 266:13141-13146 (1991)
	AP	3	Gardella, T.J., <i>et al.</i> , "Analysis of Parathyroid Hormone's Principal Receptor-Binding Region by Site-Directed Mutagenesis and Analog Design," <i>Endocrinol.</i> 132:2024-2030 (1993)

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	AK						Yes No

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ew	AL	<u>4</u>	Gardella, T.J., <i>et al.</i> , "Determinants of [Arg ²]PTH-(1-34) Binding and Signaling in the Transmembrane Region of the Parathyroid Hormone Receptor," <i>Endocrinol.</i> 135:1186-1194 (1994)
	AM	<u>4</u>	Gardella, T.J., <i>et al.</i> , "Parathyroid Hormone (PTH)-PTH-related Peptide Hybrid Peptides Reveal Functional Interactions between the 1-14 and 15-34 Domains of the Ligand," <i>J. Biol. Chem.</i> 270:6584-6588 (1995)
	AN	<u>4</u>	Gombert, F.O., <i>et al.</i> , "Alanine and D-Amino Acid Scan of Human Parathyroid Hormone," in <i>Peptides: Chemistry, Structure and Biology</i> , Pravin <i>et al.</i> , eds., Mayflower Scientific Ltd., Switzerland, pp. 661-662 (1996)
	AO	<u>4</u>	Gardella, T.J., <i>et al.</i> , "Converting Parathyroid Hormone-related Peptide (PTHrP) into a Potent PTH-2 Receptor Agonist," <i>J. Biol. Chem.</i> 271:19888-19893 (1996)
	AP	<u>4</u>	Goltzman, D., <i>et al.</i> , "Analysis of the Requirements for Parathyroid Hormone Action in Renal Membranes with the Use of Inhibiting Analogues," <i>J. Biol. Chem.</i> 250:3199-3203 (1975)

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 To be assigned — 4646

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	AA5					
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						Yes
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	AI					Yes
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	AJ					Yes
						No
	AK					Yes
						No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

ew	AL	5	Goud, N.A., <i>et al.</i> , "Solid-Phase Synthesis and Biologic Activity of Human Parathyroid Hormone (1-84)," <i>J. Bone Min. Res.</i> 6:781-789 (1991)
	AM	5	Holtmann, M.H., <i>et al.</i> , "Critical Contributions of Amino-terminal Extracellular Domains in Agonist Binding and Activation of Secretin and Vasoactive Intestinal Polypeptide Receptors," <i>J. Biol. Chem.</i> 270:14394-14398 (1995)
	AN	5	Horiuchi, N. <i>et al.</i> , "A Parathyroid Hormone Inhibitor in vivo: Design and Biological Evaluation of a Hormone Analog," <i>Science</i> 220:1053-1055 (1993)
	AO	5	Ishihara, T., <i>et al.</i> , "Molecular cloning and expression of a cDNA encoding the secretin receptor," <i>EMBO J.</i> 10:1635-1641 (1991)
	AP	5	Jelinek, L.J., <i>et al.</i> , "Expression Cloning and Signaling Properties of the Rat Glucagon Receptor," <i>Science</i> 259:1614-1616 (1993)

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	AA6					
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	AI6					Yes No
	AJ6					Yes No
	AK6					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<u>ew</u>	AL	<u>6</u>	Jüppner, H., <i>et al.</i> , "The Parathyroid Hormone-like Peptide Associated with Humoral Hypercalcemia of Malignancy and Parathyroid Hormone Bind to the Same Receptor on the Plasma Membrane of ROS 17/2.8 Cells," <i>J. Biol. Chem.</i> 263:8557-8560 (1988)
	AM	<u>6</u>	Jüppner, H., <i>et al.</i> , "The Extracellular Amino-Terminal Region of the Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Determines the Binding Affinity for Carboxyl-Terminal Fragments of PTH-(1-34)," <i>Endocrinol.</i> 134:879-884 (1994)
	AN	<u>6</u>	Karaplis, A.C., <i>et al.</i> , "Lethal skeletal dysplasia from targeted disruption of the parathyroid hormone-related peptide gene," <i>Genes & Develop.</i> 8:277-289 (1994)
	AO	<u>6</u>	Kolakowski, L.F., "GCRDb: A G-Protein-Coupled Receptor Database," <i>Receptors and Channels</i> 2:1-7 (1994)
	AP	<u>6</u>	Kronenberg, H.M., <i>et al.</i> , "Parathyroid Hormone: Biosynthesis, Secretion, Chemistry, and Action," in <i>Physiol. Pharmacol. of Bone</i> , Mundy, G.R. and Martin, T.J., eds., Springer-Verlag, Berlin pp. 508-567 (1993)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

bw	AL	Z	Lanske, B., <i>et al.</i> , "PTH/PTHrP Receptor in Early Development and Indian Hedgehog-Regulated Bone Growth," <i>Science</i> 273:663-666 (1996)
	AM	Z	Lin, H.Y., <i>et al.</i> , "Expression Cloning of an Adenylate Cyclase-Coupled Calcitonin Receptor," <i>Science</i> 254:1022-1024 (1991)
	AN	Z	Luck, M.D., <i>et al.</i> , "The (1-14) Fragment of Parathyroid Hormone (PTH) Activates Intact and Amino-Terminally Truncated PTH-1 Receptors," <i>Mol. Endocrinol.</i> 13:670-680 (May 1999)
	AO	Z	Mannstadt, M., <i>et al.</i> , "Evidence for a Ligand Interaction Site at the Amino-Terminus of the Parathyroid Hormone (PTH)/PTH-related Protein Receptor from Cross-linking and Mutational Studies," <i>J. Biol. Chem.</i> 273:16890-16896 (July 1998)
	AP	Z	Nissenson, R.A., <i>et al.</i> , "Synthetic Peptides Comprising the Amino-terminal Sequence of a Parathyroid Hormone-like Protein from Human Malignancies. Binding to Parathyroid Hormone Receptors and Activation of Adenylate Cyclase in Bone Cells and Kidney," <i>J. Biol. Chem.</i> 263:12866-12871 (1988)

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	AJ						Yes No
	AK						Yes No

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<u>Bin</u>	AL	<u>8</u>	Nussbaum, S.R., <i>et al.</i> , "Parathyroid Hormone-Renal Receptor Interactions," <i>J. Biol. Chem.</i> 255:10183-10187 (1980)
	AM	<u>8</u>	Van Ostade, X., <i>et al.</i> , "Human TNF mutants with selective activity on the p55 receptor," <i>Nature</i> 361:266-269 (1993)
	AN	<u>8</u>	Pinckard, R.N., <i>et al.</i> , "Factors Influencing the Immune Response I. Effects of the Physical State of the Antigen and of Lymphoreticular Cell Proliferation on the Response to Intravenous Injection of Bovine Serum Albumin in Rabbits," <i>Clin. Exp. Immunol.</i> 2:331-341 (1967)
	AO	<u>8</u>	Rixon, R.H., <i>et al.</i> , "Parathyroid Hormone Fragments May Stimulate Bone Growth in Ovariectomized Rats by Activating Adenylyl Cyclase," <i>J. Bone Min. Res.</i> 9:1179-1189 (1994)
	AP	<u>8</u>	Robbins, D.C., <i>et al.</i> , "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients," <i>Diabetes</i> 36:838-841 (1987)

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ew	AL	2	Rosenblatt, M., "Parathyroid Hormone: Chemistry and Structure-Activity Relations," <i>Pathobiol. Annu.</i> 11:53-86 (1981)
	AM	2	Shen, V., <i>et al.</i> , "Effects of Combined and Separate Intermittent Administration of Low-Dose Human Parathyroid Hormone Fragment (1-34) and 17 β -Estradiol on Bone Histomorphometry in Ovariectomized Rats with Established Osteopenia," <i>Calcif. Tissue Int.</i> 50:214-220 (1992)
	AN	2	Shimizu, M., <i>et al.</i> , Abstract F398, "Type-Substitution Analysis of the Amino-Terminal Fragment of Parathyroid Hormone, PTH(1-14): An Approach toward New Low Molecular Weight PTH Agonists," <i>J. Bone Min. Res. Program & Abstracts</i> 14:S289 (September 1999)
	AO	2	Slovik, D.M., <i>et al.</i> , "Restoration of Spinal Bone in Osteoporotic Men by Treatment With Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitamin D," <i>J. Bone Min. Res.</i> 1:377-381 (1986)
	AP	2	Stroop, S.D., <i>et al.</i> , "Chimeric Human Calcitonin and Glucagon Receptors Reveal Two Dissociable Calcitonin Interaction Sites," <i>Biochem.</i> 34:1050-1057 (1995)

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ew	AL	10	Takasu, H., <i>et al.</i> , "Amino-Terminal Modifications of Human Parathyroid Hormone (PTH) Selectively Alter Phospholipase C Signaling via the Type 1 PTH Receptor: Implications for Design of Signal-Specific PTH Ligands," <i>Biochemistry</i> 38:13453-13460 (1999)
	AM	10	Tregear, G.W., <i>et al.</i> , "Bovine Parathyroid Hormone: Minimum Chain Length of Synthetic Peptide Required for Biological Activity," <i>Endocrinol.</i> 93:1349-1353 (1973)
	AN	10	Turner, P.R., <i>et al.</i> , "A Putative Selectivity Filter in the G-protein-coupled Receptors for Parathyroid Hormone and Secretin," <i>J. Biol. Chem.</i> 271:9205-9208 (1996)
	AO	10	Turner, P.R., <i>et al.</i> , Abstract 121, "Single Mutations Allow the PTH2 Receptor to Respond to PTHrP," <i>J. Bone Min. Res. Program & Abstracts</i> 12:S133 (August 1997)
	AP	10	Ureña, P., <i>et al.</i> , "Regulation of Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Messenger Ribonucleic Acid by Glucocorticoids and PTH in ROS 17/2.8 and OK Cells," <i>Endocrinol.</i> 134:451-456 (1994)

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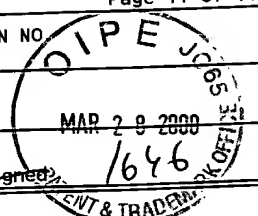
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EW	AL	11	Usdin, T.B., <i>et al.</i> , "Identification and Functional Expression of a Receptor Selectively Recognizing Parathyroid Hormone, the PTH2 Receptor," <i>J. Biol. Chem.</i> 270:15455-15458 (1995)
	AM	11	Whitfield, J.F., <i>et al.</i> , "Restoration of Severely Depleted Femoral Trabecular Bone in Ovariectomized Rats by Parathyroid Hormone-(1-34)," <i>Calcif. Tissue Int.</i> 56:227-231 (1995)
	AN	11	Whitfield, J.F., <i>et al.</i> , "Stimulation of the Growth of Femoral Trabecular Bone in Ovariectomized Rats by the Novel Parathyroid Hormone Fragment, hPTH-(1-31)NH ₂ (Ostabolin)," <i>Calcif. Tissue Int.</i> 58:81-87 (1996)
	AO	11	Whitfield, J.F., <i>et al.</i> , "Comparison of the Ability of Recombinant Human Parathyroid Hormone, rhPTH-(1-84), and hPTH-(1-31)NH ₂ to Simulate Femoral Trabecular Bone Growth in Ovariectomized Rats," <i>Calcif. Tissue Int.</i> 60:26-29 (January 1997)
	AP	11	Whitfield, J.F. and Morley, P., "Small bone-building fragments of parathyroid hormone: new therapeutic agents for osteoporosis," <i>Trends in Pharmacol. Sci.</i> 16:382-386 (1995)

EXAMINER

EW

DATE CONSIDERED

10/16/02

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.